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Application No.: 10/724,458

Docket No.: BEW-005

REMARKS

Claims 1-24 were presented for examination, of which claims 1 and 13 are independent claims. Claims 1 and 13 have been amended. No new matter has been added. The following comments address all stated grounds for objection or rejection, and place the presently pending claims, as identified above, in condition for allowance.

Claim Amendments

Claim 1 has been amended to recite "determining whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value." Claim 13 has been amended to recite "an electrode assessment module for determining whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value." Support for claim amendments can be found throughout the specification and specifically paragraph [0015] and paragraph [0052] of the present Application Publication No. 2004/0243018.

Applicants further amend claim 1 to improve the readability of the claim.

Claim Objections

Claims 1-2, 4-14 and 16-24 are objected to because of informalities. Applicants amend claims 1 and 13 to recite "one current injection electrode of a current injection electrode pair and one proximal voltage measurement electrode of a voltage measurement electrode pair." Applicants respectfully submit that the claim amendments address the lack of antecedent basis informalities. Applicants further amend claim 4 to depend from claim 2. Applicants amend claim 16 to depend from claim 14 to address the Examiner's objections.

Applicants respectfully request the Examiner to reconsider and withdraw the objections to claims 1-2, 4-14 and 16-24.

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Claims Rejected under 35 U.S.C. § 103(a)**Claims 1-2, 7-11, 13-14 and 19-23**

Claims 1-2, 7-11, 13-14 and 19-23 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,122,544 to Organ (hereafter "Organ") in view of U.S. Patent No. 6,391,024 to Sun et al. (hereafter "Sun"). Applicants respectfully traverse these rejections.

Neither Organ nor Sun, alone or in combination, teach or suggest determining *whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value.*

Organ teaches scanning the presence (or absence) of breast anomalies, particularly benign and malignant tumors based on the organ's impedance characteristics. *See* Col. 2, lines 22-32. Organ teaches that electrical impedance is measured by using four electrodes. *See* Col. 4, lines 14-15. Organ further teaches that the electrodes are attached to the skin side of a main section of an array and are made of an electrically conductive, self adhesive material so that when the array is positioned in the skin and pressed against it, the adhesive quality of the electrodes assures good skin fixation. *See* Col. 4, lines 49-54. Organ does not teach or suggest an electrode assessment measurement to ensure the placement of the electrodes. Furthermore, Organ provides that regardless of the electrode arrangement, four electrodes must be used to make measurements (e.g., a tetrapolar measurement). *See* Col. 4, lines 46-49. In contrast to Organ, the claimed invention provides *bipolar* electrode assessment measurements. Organ, therefore, fails to teach or suggest making an electrode assessment measurement, as a *bipolar* measurement. As such, Organ does not teach or suggest determining *whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value*, as recited by claims 1 and 13.

Sun teaches assessing the adequacy of contact between ablation electrode carried by an electrode and biological tissue within a biological organ having biological fluid therein. Sun teaches positioning the ablation electrode in the in the biological fluid; positioning a reference electrode at a distance from the first electrode and obtaining a reference impedance value by measuring the impedance between the ablation electrode and the reference electrode. Sun further teaches moving the ablation electrode to a position near or next to the biological tissue;

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obtaining an assessment impedance value by measuring the impedance between the ablation electrode and the reference electrode; analyzing the assessment impedance and the reference impedance; and indicating the state of electrode/tissue contact. *See* Col. 3, lines 37-50. As such, Sun requires calculating at least two impedances to determine the adequacy of contact. A comparison is made of the two measurements in order to determine the adequacy of contact. In contrast, claims 1 and 13 recite one bipolar electrode assessment measurement that is compared to a known value to determine the quality of contact. Sun, alone or in combination with Organ does not teach or suggest determining whether *the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value.*

For at least these reasons, Applicants respectfully contend that neither Organ nor Sun teach or suggest, alone or in combination, all of the patentable features of claims 1 and 13, as amended. Claims 2, 7-11 depend, directly or indirectly, from claim 1, and therefore incorporate all of the patentable features of claim 1. Claims 14, 19-23 depend, directly or indirectly, from claim 13, and therefore incorporate all of the patentable features of claim 13. Applicants respectfully request the Examiner to reconsider and withdraw the rejections of claims 1, 2, 7-11, 13-14 and 19-23 under 35 U.S.C. § 103(a).

Claims 12 and 24

Claims 12 and 24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Organ in view of Sun further in view of U.S. Patent No. 5,419,337 to Dempsey et al. (hereafter "Dempsey"). Applicants respectfully traverse these rejections.

Organ, Sun and Dempsey, alone or in combination, do not teach or suggest determining *whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value.*

Dempsey teaches a display to serve as means of interpreting the quality of the signals of each group of channels for determining which electrodes may have poor skin contact. *See* Col. 5, lines 21-25. It appears that Dempsey teaches a system where a user must use his own judgment to interpret data from a display to determine whether electrodes may have poor skin contact. Furthermore, the ECG system discussed in Dempsey, by its nature, typically only has one

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type of electrode. In contrast, claims 1 and 13 recite determining *whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value.*

For at least these reasons, Applicants respectfully contend that Organ, Sun and Dempsey, alone or in combination, do not teach or suggest all of the patentable features of claims 1 and 13, as amended. Claim 12 depends from claim 1 and therefore incorporates all of the patentable features of claim 1. Claim 24 depends from claim 13, and therefore incorporates all of the patentable features of claim 13. Applicants respectfully request the Examiner to reconsider and withdraw the rejections of claims 12 and 24 under 35 U.S.C. § 103(a).

Claims 4-6 and 16-18

Claims 4-6 and 16-18 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Organ in view of Sun further in view of U.S. Patent No. 5,372,141 to Gallup et al. (hereafter "Gallup"). Applicants respectfully traverse these rejections.

Organ, Sun and Gallup, alone or in combination, do not teach or suggest a determining *whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value.*

Gallup discusses a body composition analyzer including a number of electrodes attachable to the body of a person. See Col. 1, lines 45-47. In contrast to the bipolar electrode assessment recited in claims 1 and 13, Gallup teaches a tetrapolar electrode arrangement. Gallup specifies the location of each electrode in the tetrapolar electrode. See Col. 4, lines 7-23. However, Gallup does not teach or suggest determining *whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value.*

For at least these reasons, Applicants respectfully contend that Organ, Sun and Gallup, alone or in combination, do not teach or suggest all of the patentable features of claims 1 and 13, as amended. Claims 4-6 depend from claim 1 and therefore incorporates all of the patentable features of claim 1. Claims 16-18 depend from claim 13, and therefore incorporates all of the

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patentable features of claim 13. Applicants respectfully request the Examiner to reconsider and withdraw the rejections of claims 4-6 and 16-18 under 35 U.S.C. § 103(a).

Claims 4-6 and 16-18

Claims 4-6 and 16-18 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Organ in view of Sun further in view of U.S. Patent No. 5,788,643 to Feldman et al. (hereafter "Feldman"). Applicants respectfully traverse these rejections.

Organ, Sun and Feldman, alone or in combination, do not teach or suggest determining *whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value.*

Feldman teaches applying electrodes to the body parts of a patient then passing a high frequency current between the electrodes to detect warnings of heart failure. *See* Col. 5, lines 25-28. Feldman teaches the body parts where the electrodes need to be placed. However, Feldman does not teach or suggest determining *whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement to a known value.* Feldman simply indicated that once the electrodes have been properly attached to the patient, a high frequency current is passed between the electrodes. *See* Col. 5, lines 10-12.

For at least these reasons, Applicants respectfully contend that Organ, Sun and Feldman, alone or in combination, do not teach or suggest all of the patentable features of claims 1 and 13, as amended. Claims 4-6 depend from claim 1 and therefore incorporates all of the patentable features of claim 1. Claims 16-18 depend from claim 13, and therefore incorporates all of the patentable features of claim 13. Applicants respectfully request the Examiner to reconsider and withdraw the rejections of claims 4-6 and 16-18 under 35 U.S.C. § 103(a).

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CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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